UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,641	02/28/2002	Michael L. Blomquist	9015.148US01	6999

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EXAMINER
FRANK, ELLIOT L

ART UNIT	PAPER NUMBER
2125	4

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/086,641	BLOMQUIST, MICHAEL L.
	Examiner	**Art Unit**
	Elliot L Frank	2125

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
 after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
 earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002*.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
 closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:
      1.☐ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
        application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.
 37 CFR 1.78.

    a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific
 reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: .

DETAILED ACTION

Drawings

1. New formal drawings will be required subject to the allowance of this application.

   Figures 1-30e were hand drawn and/or numbered. These drawings do not conform

   to the patent office requirements. While these drawings are acceptable for the

   examination of the application, pending allowance the applicant is advised to employ

   the services of a competent patent draftsperson outside the Office, as the Patent

   and Trademark Office no longer prepares new drawings.

Specification

2. There are many instances in the specification where the applicant has omitted

   copending application or patent number information. Please update these omissions

   with the current available information. Missing citations have been noted as follows:

   a. Page 1, Reference to copending applications

   b. Page 7, line 17

   c. Page 9, line 18

   d. Page 15, line 2

3. The lengthy specification has not been checked to the extent necessary to

   determine the presence of all possible minor errors. Applicant's cooperation is

   requested in correcting any errors of which applicant may become aware in the

   specification.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bylund

et al. (US 2003/0212379 A1).

The aforementioned claims, as well as the relevant citations in Bylund et al. are

as follows:

1. A method of delivering a bolus from a pump, the pump being a programmable

medical infusion pump having a keypad (page 1, paragraph 0007), the method

comprising:

programming a bolus amount into the pump;

programming a duration into the pump; programming a percentage into the

pump, the percentage defining a portion of the bolus amount to deliver immediately

upon executing a deliver command and a remainder of the bolus amount to deliver

over the duration upon executing a deliver command (the programming of a

percentage to control the amount of bolus administered by the pump is considered

obvious in view of page 2, paragraph 0011, wherein Bylund et al. explains the

flexibility of the user to change a pump setting at any time, combined with page 4,

paragraphs 0046-0050, wherein the configuration of a pump display and key

interface is described that can be customized based on the desired functionality of

the application); and

executing the deliver command (page 9, paragraph 0095).

2. The method of claim 1 wherein programming a percentage into the pump

includes entering into the pump the portion of the bolus amount to deliver

immediately upon executing a deliver command (page 9, paragraph 0095).

3. The method of claim 1 wherein programming a percentage into the pump

includes entering into the pump the remainder of the bolus amount to deliver over

the duration upon executing the deliver command (page 9, paragraph 0095).

4. The method of claim 1 wherein executing the deliver command causes the

pump to begin delivery of the bolus, the bolus being insulin (page 8, paragraph

0091).

5. The method of claim 4 further comprising delivering a basal, wherein

executing the deliver command causes the pump to begin delivery of the bolus, the

bolus being in addition to the basal (page 4, paragraph 0046).

6. An apparatus for delivering a bolus of a medical agent to a patient, the

apparatus comprising: a pump mechanism; a data input device; and a processor in

data communication with the keypad and arranged to control the pump mechanism,

the processor being programmed to receive data specifying a bolus amount through

the data port, receive data regarding duration through the data port, receive a

percentage through the data port, the percentage defining a portion of the bolus

amount to deliver immediately upon executing a deliver command and a remainder

of the bolus amount to deliver over the duration upon executing a deliver command,

and execute the deliver command thereby controlling the pump mechanism to

deliver the bolus (Claim 6 has the same functional limitations as claim 1 with the

addition of interface and control requirements for the pump. The claim is obvious in

view of the same citations as claim 1 with the addition of page 4, paragraph 0047-

0050 wherein Bylund et al. describes the required hardware).

7. The apparatus of claim 6 wherein the data input device is a keypad having

one or more buttons (page 4, paragraph 0049).

8. The apparatus of claim 6 wherein the data input device is a data port

configured to communicate with a computer (page 7, paragraph 0080).

9. The apparatus of claim 6 wherein the processor is further programmed to

control the pump mechanism to simultaneously deliver a basal and the bolus upon

executing the deliver command (page 10, paragraph 0111).

10. A method of temporarily adjusting the delivery rate of an infusion pump, the

infusion pump programmed to deliver a basal rate (page 8, paragraph 0086), the

method comprising:

prompting a user to select whether to enter the temporary rate as a percent of

the current delivery rate or as a new delivery rate (the programming of a percentage

to control the amount of bolus administered by the pump is considered obvious in

view of page 2, paragraph 0011, wherein Bylund et al. explains the flexibility of the

user to change a pump setting at any time, combined with page 4, paragraphs 0046-

0050, wherein the configuration of a pump display and key interface is described

that can be customized based on the desired functionality of the application);

entering into the pump a period of time having a beginning and an end; entering into

the pump a temporary basal rate; and delivering the therapeutic agent at a delivery

rate substantially equal to the temporary basal rate during the period of time (page 9,

paragraph 0095).

11. The method of claim 10 further comprising: selecting to enter the temporary

basal rate as a new delivery rate; and wherein entering into the pump a temporary

basal rate includes entering into the pump a new delivery rate, thereby changing the

basal rate to the new delivery rate for period of time (page 9, paragraph 0095).

Claims 12-14 require entering various pump control parameters in the form of

percentages of the current rate. The programming of a percentage to control the

amount of bolus administered by the pump is considered obvious in view of page 2,

paragraph 0011, wherein Bylund et al. explains the flexibility of the user to change a

pump setting at any time, combined with page 4, paragraphs 0046-0050, wherein

the configuration of a pump display and key interface is described that can be

customized based on the desired functionality of the application

15. The method of claim 12 further comprising: delivering a therapeutic agent at

a delivery rate substantially equal to the basal rate before the beginning of the period

of time; and delivering the therapeutic agent at the delivery rate substantially equal

to the basal rate after the end of the period of time (page 8, paragraphs 0086-0088).

Claim 16 requires determining a temporary delivery rate based on an entered

percentage of the current rate. This technique is a simple equation for determining

the percentage of a base value and is considered well known in the art. The programming of a percentage to control the amount of bolus administered by the pump is considered obvious in view of page 2, paragraph 0011, wherein Bylund et al. explains the flexibility of the user to change a pump setting at any time, combined with page 4, paragraphs 0046-0050, wherein the configuration of a pump display and key interface is described that can be customized based on the desired functionality of the application.

Claims 17-19 have the same functional requirements as previously rejected claims 10-12. Therefore, these claims are also rejected as obvious in view of the same citations in Bylund et al.

20. The apparatus according to claim 17 further comprising a reservoir arranged to be emptied by the pump mechanism, the reservoir being filled with insulin (page 3, paragraph 0038, wherein the application of insulin delivery is recited and paragraph 0042, wherein the reservoir is recited.

Claims 21 and 22 have the same functional requirements as previously rejected claims 7 and 8. Therefore, these claims are also rejected as obvious in view of the same citations in Bylund et al.

23. The apparatus of claim 20 further comprising a screen in data communication with the processor, wherein the processor is programmed to display the prompt on the screen (page 4, paragraph 0046).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure:

US 2002/0065509 A1 – Lebel et al. – Drug pump

US 2003/0114836 A1 – Estes et al. – Drug pump

US 2003/0199854 A1 – Kovach et al. – Drug pump

US 2003/0212364 A1 – Mann et al. – Drug pump

USPN 4,392,849 – Petre et al. – Drug pump

USPN 5,745,378 A – Barker et al. – Drug pump

USPN 6,539,250 B1 – Bettinger – Drug pump

USPN 6,659,978 B1 – Kasuga et al. – Drug pump

7. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Elliot L Frank whose telephone number is (703) 305-

5442. The examiner can normally be reached on M-F 7-4:30, 1st Friday off.

    If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Leo P Picard can be reached on (703) 308-0538. The fax phone number

for the organization where this application or proceeding is assigned is 703-872-

9306.

    Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is (703)

306-5484.

Art Unit: 2125

ELF
December 24, 2003

LEO PICARD
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